

08-31-00

PATENT APPLICATION TRANSMITTAL LETTER
(Small Entity)

A

Docket No.
RES-101A

TO THE ASSISTANT COMMISSIONER FOR PATENTS

Transmitted herewith for filing under 35 U.S.C. 111 and 37 C.F.R. 1.53 is the patent application of:

For: **Ophthalmic Device and Method of Manufacture and Use**

Enclosed are:

- ☒ Certificate of Mailing with Express Mail Mailing Label No. **EL571265305US**
- ☐ sheets of drawings.
- ☐ A certified copy of a application.
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Dated: August 30, 2000

Please address all correspondence to:

Thomas M. Saunders
Lorusso & Loud
440 Commercial Street
Boston, MA 02109


Signature

Thomas M. Saunders Reg. No. 29,585
Lorusso & Loud
440 Commercial Street
Boston, MA 02109

cc:

OPHTHALMIC DEVICE AND METHOD OF MANUFACTURE AND USE

Field of the Invention

5 This invention relates to presbyopia and in particular, it relates to a torsion-resistant scleral-tensioning device and further including a method of chronic ocular fluid control utilizing such device.

Background of the Invention

10 Without being bound by any particular theory, recent studies in ophthalmology suggest that presbyopia that arises almost universally among people in their 40s is the result of the continued growth of the lens. Lens growth results in shortening the length between the lens and ciliary muscles. This compromises the ability of the ciliary muscles to effectively stretch the lens. This is exhibited as
15 a reduced amplitude of accommodation. The increasing the effective working distance between the ciliary muscles and the lens equator is effected by increasing the diameter of the sclera in the region of the ciliary body. This theory is not confirmed and other or additional factors may obtain.

 Astigmatism is another prevalent visual problem. Astigmatism occurs when
20 light entering the eye is "split" into two separate parts instead of focusing to one, precise point on the retina. Astigmatism usually occurs because of a corneal irregularity. Historically, a lens with two different power curves (toric lens) has been employed to correct astigmatism. In practice, these lenses have a variable

edge profile that is thinner in some places and thicker in others. Some amounts of astigmatism are corrected surgically in patients with astigmatism alone or astigmatism present with nearsightedness. There is no present procedure to correct astigmatism combined with farsightedness.

5 The cornea accounts for about 70% of the eye's focusing power. By altering the shape and power of the cornea, the optical characteristics of the eye can be changed. This is the basis for most refractive surgical procedures.

10 In the practice of this invention, astigmatism (with or without near or farsightedness) is ameliorated by placement of stents proximate to but not in the corneal visual pathway.

 The sclera is an element of the fibrous tunic of the eye (along with the cornea). The sclera ranges from about 0.13 to 1 mm in thickness. The tendons of the eye muscles insert on the sclera.

15 Summary of the Invention

 This invention comprises a torsion resistant scleral-tensioning stent for positioning in a tunnel formed intrasclerally in a globe of an eye, comprising a generally t-shaped body as seen in the intersection arms and having a cross portion (proximal end) with a bottom surface which is optionally flat in some embodiments
20 and a leg portion extending substantially perpendicularly from a side surface of said cross portion, the leg portion having a bottom surface with an arcuate portion and a substantially planar portion at an end of the leg portion distal from said cross

portion (distal end), wherein the arcuate portion has a curvature greater than a radius of curvature of the globe of the eye in the area of the tunnel, whereby at least a portion of the arcuate bottom surface is adapted to increase the diameter of the scleral size adjacent to the tunnel when the stent is positioned in the tunnel; and wherein the bottom surface of the cross portion is dimensioned to be disposed external to the tunnel for resisting torsional forces on the leg portion. In some embodiments the cross portion extends beyond the tunnel. In particular embodiments the arcuate stent has a base curve of from about 8 to about 9 mm, and optionally a peak of about 7 mm. Particular stents are out-gassing free, and reference is made to stents of thermosetting PMMA.

In some embodiments the stent slopes sharply from a maximum height at the leg-portion to a minimum thickness at the cross portion.

Particular embodiments of the stent are arcuate biased, and optionally in these embodiments a linear bore hole extends from the flange through the body of the stent, with the stent provided with a removable stylet positioned within the bore hole.

In specific embodiments a separate element comprises an anti-torsion-cap adapted and configured to conform to the distal end of said stent.

In some embodiments the distal end of the stent comprises an insertion blade, which is optionally removable.

Some stents of the present invention further comprising affixation means notches.

An aspect of the present invention is a torsion resistant scleral-tensioning multi-arcuate-stent comprising at least about four torsion resistant scleral-tensioning stents positioned about equidistant about the sclera, and in non-circulatory-compression arcs.

5 This invention includes a method of chronically increasing ocular fluid drainage by the steps of placing at least two torsion resistant scleral-tensioning arcuate-stents and preferably at least about four torsion resistant scleral-tensioning stents positioned about equidistant about the sclera, and in non-circulatory-compression arcs.

10 This invention also includes a method of chronically reducing ocular fluid out-flow resistance by the steps of placing at least two torsion resistant scleral-tensioning arcuate-stents and preferably at least about four torsion resistant scleral-tensioning stents positioned about equidistant about the sclera, and in non-circulatory-compression arcs.

15 This invention additionally includes a method of chronic glaucoma palliation by the steps of placing at least two torsion resistant scleral-tensioning arcuate-stents and preferably at least about four torsion resistant scleral-tensioning stents positioned about equidistant about the sclera, and in non-circulatory-compression arcs. Glaucoma, ocular hypertension, and particularly open angle glaucoma are
20 controlled by increasing frequency and maximum excursion of lens movement by increasing amplitude of lens shape change in daily use. Without being bound by

any particular theory it is believed that opening the canal of Schlemm is palliative of glaucoma.

A noted embodiment of the invention is a method of presbyopia palliation by the steps of placing at least two torsion resistant scleral-tensioning arcuate-stents and preferably at least about four torsion resistant scleral-tensioning stents
5 positioned about equidistant about the sclera, and in non-circulatory-compression arcs.

An additional embodiment of the invention comprises a method of avoiding, delaying, or reversing the lens opacification by the method of placing at least two
10 and preferably four scleral-tensioning arcuate-stents positioned

- (i) about equidistant about the sclera, and
- (ii) in non-circulatory-compression arcs.

A yet further embodiment of the invention comprises a method of astigmatism reduction by the steps of placing at least one torsion resistant scleral-
15 tensioning arcuate-stent in an intra-scleral position proximate to the lens and beyond the visual pathway to advance the outward surface of a lens in the quadrant nearest the stent.

Brief Description of the Drawings

FIG. 1(a) is a top plan view of a scleral stent, one embodiment, of the
20 present invention.

FIG. 1(b) is a side elevational view thereof;

FIG. 1(c) is a section view according to section line A-A of Fig. 1b.

FIG. 1(d) is a rear elevational view of the scleral stent of Fig. 1(a);

FIG. 1(e) is a semi-perspective view showing a stent protruding from a scleral tunnel;

FIG. 1(f) is a side elevation in cutaway showing a stent protruding from a
5 scleral tunnel;

Fig. 2 is a semi-perspective view of a modified embodiment of the scleral stent of Fig. 1(a) having reduced taper in the top to bottom direction at the rear end thereof;

Fig. 3(a) is a top plan view of a modified stent flange;

Fig. 3(b) is a rear view of the modified stent flange of Fig. 3(a);

Figs. 4(a) and 5(b) are respectively top and side views of another
embodiment of the scleral stent of the invention;

Figs. 5(a) and 5(b) are respectively top plan and side elevational views of a modified front end portion of the stent showing an anti-torsion element.

Fig. 5 (c) and 5 (d) illustrate an expandable tip arrangement;

Fig. 6(a) is a semi-perspective view of a further embodiment of a stent made of a resilient material utilizing a removable stylet for maintaining its linear configuration;

Fig. 6(b) is a semi-perspective view of the stent of Fig. 6(a) with the stylet
20 removed;

Fig. 7(a) is a view of yet another embodiment of the stent having a blade tip;

Fig. 7(b) is a side view of the blade tip of Fig. 7(a);

Fig. 7(c) is a semi-perspective view of the stent of Fig. 7(a) showing blade tip in phantom;

Fig. 7(d) is a semi-perspective view of the blade tip assembly;

Fig. 8 is a semi-perspective view of a modified stent having a suture placement arrangement;

Fig. 9(a)- 9(c) are rear elevational views of the stent of the invention with force lines showing on-axis and off-axis loading.

Fig. 10 is a rear elevational view of a non-torsion resistant stent of the prior art illustrating application of forces;

Fig. 11 is a front elevational view of the ocular globe showing location of the stents;

Fig. 12(a) is a top plan view of a further embodiment of the scleral stent of the invention having textured surfaces;

Fig. 12(b) is a side elevational view of the scleral stent of Fig. 12(a);

Fig. 12(c) is a bottom plan view of the scleral stent of Fig. 12(a);

Fig. 13(a) is a top plan view of still another embodiment of the textured scleral stent of the present invention;

Fig. 13(b) is a side elevational view of the scleral stent of Fig. 13(a);

Fig. 13(c) is a bottom view of the scleral stent of Fig. 13(a);

Fig. 14 (a) is a view illustrating various textural features of the invention;

Fig. 14 (b) is a view illustrating further stent textures of the invention;

Fig. 14 (c) is a view illustrating yet another textural feature of the invention;

Fig. 15 is a view illustrating a further form of stent texture of the invention;

Fig. 16 is a semi-perspective view illustrating a "pull-through" assembly of the invention;

Fig. 16(a) is a top plan view illustrating the stent of the "pull-through"

5 assembly; and

Fig. 16(b) illustrates a stent pulling device.

Detailed Description of the Invention

Definitions

10 A. Stents of this invention are dimensioned from about 2 mm to about 6 mm, in length with particular reference to about 4.75 to about 5 mm. In particular embodiments the stents are tapered from the sides with a narrow end of about 550 microns to about 650 microns and a wide end of about 600 to about 850 microns adjoining a flange of about 1000 to about 15 hundred microns with particular
15 reference to about 1200 microns. Stents with the long axis generally describing and arc are noted with a radii at the upper surface of from about 3 to about 10 mm with particular reference to about 4.0 to about 4.7 mm and particularly about 4.4 mm. Stents with the long axis generally describing and arc are noted with a radii at the lower surface of from about 3 to about 15 mm with particular reference to
20 about 7 to about 10 mm and particularly about 8.8 mm.

B. Scleral-tensioning as to a stent shall mean a support structure that elevates or "tents" the sclera thus expanding the globe. Scleral-tensioning increases lens zonule tensioning.

C. Arcuate as to a stent shall mean substantially all weight bearing contact inward to the sclera is borne at the ends of the stent. While arcuate applies to stents comprising an arc as a segment of circle, arcuate shall be broadly construed to include any structure that provides for substantially all weight bearing contact inward to the sclera is borne at the ends of the stent. In one embodiment the radius of the curvature is from about 9.5 to 8 mm and particularly about 9 mm and 8.8 mm. In one stent the top surface is about 5 mm at the ends rising to about 9 mm at the center.

D. Presbyopically-effective scleral tensioning is achieved when the total tenting is from about 250mm and further at least about 400, and particularly about 500 to about 700 mm or more. Lesser amounts of tenting can be effective.

E. Efflux-effective tensioning shall mean total tenting from about 200mm, but further includes 250mm and further at least about 400, and particularly about 500 to about 700 mm or more. Efflux-effective tensioning is useful in controlling pressure buildup in the anterior chamber of the eye associated with glaucoma. Chronic open angle glaucoma is characterized at intra ocular pressures above about 20 to 24 mm Hg. Controlled glaucoma is about 20 and preferable 16 mm Hg or less. It is noted that even low tension glaucoma is treated by the present invention reducing intra ocular pressures from about 14 to 20 mm Hg to about 10 mm Hg.

F. Torsion-resistance is provided by mechanical means such as a flange and with an optional flat foot rather than a round bottom stent. Torsion resisting structural features are broadly termed torsion resistance elements.

Referring now to Fig. 9 which is a rear view of a stent of the invention similar to that of Fig. 1(a). Orientational stability as seen through flange (96) is resistance to off-axis forces (99) as the sclera adjusts, moves, or deforms. Ignoring slippage, compression, and wedging effects, the stent will tend to rotate about its longitudinal axis when the axis of the net force does not pass through the base of the stent. (Figure 9(b).) There is a critical angle running through a point (α) for any applied net-load beyond which the stent will tend to be unstable. In this respect, refer to (Figure 9(c)). The maximum stent height, the length, the radius of curvature, the height of the flange, and the width of the flange determine this critical angle.

In an embodiment of the present invention substantially as shown in Fig. 1(a) with a length of 5000 μ , a radius curve of 8800 μ , and height of flange of 500 μ and given a flange width of 1200 microns the orientation-stability on off-axis load is about 35°. The same stent with no flange possesses a far diminished orientation-stability of about 20° off-axis loading. The same stent with a rounded bottom has orientation-stability of about 10° off-axis loading.

Fig. 10 is a rear view of a round bottom unflanged stent (106). Off-axis forces are indicated by an arrow (99). Therefore, torsion-resistance of the present

invention particularly notes a factor superiority of about 1.8 over no-flange unaffixed stents and about 3.5 over rounded bottom unaffixed stents.

If the stent height is increased, for example to provide more tenting, maintaining equivalent stability is optionally achieved by increasing the width of the base by a proportionate amount in order to maintain a given orientation-stability.

Consider an embodiment with a flange width of 1200 microns, and a total height (from the arc length plus the flange height) of 862 microns. To increase tenting another 100 microns and maintain the same orientation-stability the flange width is increased to 1339 microns. That is, the ratio of Flange to Width to maximum height is held constant (*e.g.*, $1200/862$ and $1339/962$).

Other means of maintaining torsion resistance include biocompatible adhesives and mechanical fasteners such as staples and sutures.

In some embodiments sutures are be applied, particularly at the extremes of the wide footprint, so as to avoid slipping. In the embodiment of Fig. 8, sutures are applied to maintain contact of the flange to the sclera. When sutured, the bottom of the wide flange will tend to support the on-axis component of the net load and the sutures will only have to support any cross-axis component of force. Only if the net-force is applied beyond the critical angle it is necessary for sutures to support any off-axis component of the load to prevent rotation. A wide flange will tend to reduce the force exerted on the sutures.

Fig. 11 is a view of the ocular globe (200) with intrasclerally implanted devices. The outer layer of the eye is the sclera (202) and the external muscles

(218). The cornea (214) is the most anterior structure with the pupil (224) seen behind and central thereto. The limbus (216) is the junction of sclera (202) and cornea (214). Tunnels (220) in the sclera are seen with anterior margins (222) about 4 to 5 millimeters posterior to the limbus (216). Each tunnel (220) contains
5 the stent (204) having the front end (207) protruding from one end thereof and a flange (206) protruding from the other end. The body (205) of the stent positioned within the tunnel is shown in phantom. The stent is oriented with its protruding front end (207) and flange (206) resting on the sclera and its arcuate peak (205) within the tunnel.

10 In particular embodiments the torsion-resistant flange of this invention is chronically stable, maintaining maximal tenting for at least about one year, and preferable for about 8 years and in particular embodiments for in excess of 10 years.

15 Stents of the present invention can be fashioned of any suitable material with attention to bio-compatibility. For example poly-methyl methacrylate ("PMMA"), both thermoset and thermoplastic, are suitable. PMMA is supplied by a number of sources. Thermosetting PMMA is available as Perspex CQ (ICI Derby, England). Thermosetting PMMA is preferred over thermoplastic PMMA because it is out-gassing free. That is, it does not release monomers *in situ*. Teflon® and
20 tantalum are also noted. It is also possible to coat stents with bio-compatible materials if elements of the stent are not bio-compatible. In some embodiments the stent materials contain pigments or dyes. In particular embodiments stents are

coated or impregnated with bioactive substances including anti-inflammatory agents/immunomodulating agents and antiinfective agents. Particular stents will contain radio-opaque, radioactive, fluorescent, NMR contrast or other "reporter" materials. Smooth stents with no more than 100 Å peak to valley are noted. A particular advantage of such a smooth surface is the reduction of implant erosion into or out of the sclera. In particular embodiments textured stents are useful permitting adhesion with associated tissues.

Preferably, placement of the stents is adjusted to avoid compression of the ciliary arteries. Placement is preferred at about the 2:00, 4:00, 8:00 and 10:00 positions around the globe. Such placement comprises non-circulatory-compression arcs. Placement compressing the ciliary arteries can be detected by occurrence of anterior segment ischemia. For stent elements overlying ciliary arteries, compression of ciliary arteries is minimized by increased surface area of portions of the stent pressing inward on the eye. In some embodiments it is useful to place stents anywhere from about 3 to about 8 mm and preferably about 4 to 6 mm posterior to the limbus in the oblique quadrants of the eye at a depth of about 250 to 300 microns within scleral tunnels that are about 3 to 5 mm long and preferably about 3.8 to 4.0 mm long.

Referring now to Figs. 1(a) - 1 (d), which illustrate one embodiment of the scleral tensioning stent of the invention. A torsion resistant scleral-tensioning stent 2 of the invention is adapted for positioning in a tunnel formed in a sclera of an eye. The stent (2) comprises a generally T-shaped body having a torsion-resistant

element, a flange or a cross portion (6) formed with a substantially flat rear bottom surface (10) and a leg portion (4) extending outwardly from a side surface of the portion and having a substantially flat front bottom surface (8). The leg portion (4) is formed with a bottom area having an arcuate region (7) which
5 extends rearwardly from the front bottom surface (8) so that its rear end is situated in the close vicinity to the cross-portion (6). A curvature of the arcuate region (7) is greater than the curvature of the globe in an area of the tunnel. Thus, at least a portion of the arcuate region (7) is adapted to increase the diameter of the scleral size adjacent the tunnel when the stent is positioned within the tunnel. Upon
10 proper positioning of the stent of the invention, the rear bottom surface (10) of the cross portion (6) is adapted to be disposed externally to the tunnel for resisting torsional forces on the leg portion.

As best illustrated in Figures 1 (a) and 1 (b), the stent (2) in general and a top area thereof in particular are formed with a front tapered region (12) and a rear tapered region (14). The front tapered region 12 extends rearwardly from a
15 rounded front tip (16) of the leg portion (6) and is provided to facilitate insertion of the stent into the tunnel during the surgery. The rear tapered region (14) slopes downwardly from an area in the vicinity of the junction between the cross portion (6) and the leg portion (4) toward the rear end of the stent.

20 Fig. 2. is a perspective view of the scleral stent (2) of Fig. 1(a). The leg portion (4) of the stent is tapered at the front end (16). The torsion-resistant element or flange (6) is about 1200 microns in width, whereas the length of the

portion (10) is about 500 microns. The length of the front torsion-resistant element (8) is about 500 microns.

Fig. 3(a) represents a top partial view of another embodiment of a scleral stent of the present invention. A partially shown leg portion (34) is connected to the cross-member or flange (36) having configuration resembling a butterfly. It is clear from Fig. 3 (a), that parts of the flange (36), situated in the vicinity of the leg portion (34) are substantially narrower than parts of the flange remote from the leg.

Fig. 3(b) is a rear elevational view showing another embodiment of a flange (36) with upward curling edges (38), so as to form grooves or recesses in its upper area.

Fig. 4(a) represents a top view of a further embodiment of a scleral stent of the present invention. The leg portion (44) extends between a front region (48) and a torsion-resistant element or flange (46). Similar to the previously described embodiments, the stent (40) comprises a generally T-shaped body having the flange (46) with a rear planar or substantially flat bottom surface (47) and a leg portion (44) extending substantially perpendicularly from a side surface of the flange portion (46). The leg portion (44) is formed at a bottom part thereof with an arcuate region (45) and a substantially flat surface (48) at the front end thereof.

As illustrated in Fig. 4 (b), which is a side elevational view of the stent, the leg portion 44 contains a raised or arcuate portion (45) having a curvature or clearance greater than the curvature of the globe in an area of the tunnel. Thus, at least a portion of the arcuate bottom surface is adapted to increase the diameter of the

scleral size adjacent the tunnel when the stent is positioned there inside.

Furthermore, the near planar or substantially flat surface (47) of the cross portion (46) is designed to be disposed externally to the tunnel for resisting torsional forces on the leg portion.

5 As illustrated in Figures 4 (a) and 4 (b), the torsion-resistant element (46) and the front end of the leg portion (44) are formed having the height substantially smaller than the height of the central area of the stent. The leg portion (44) contains intermediary elements (41) and (43), which connect its top surface (42) with the front end (48) and the torsion-resistant or flange element (46) respectively. As illustrated in Figure 4 (b), the intermediary portions (41) and (43) are sloped sharply from the maximum height of the leg portion in the central area thereof to a minimum height of the stent at the extremities (48) and (46).

10 The scleral-tensioning stent of the present invention can be formed with a torsion resistant arrangement other than the above discussed flange or cross-portion. In this respect Fig. 5 (a) illustrates a top-view of an anti-torsion-cap (50) adapted to engage a front end of the stent (54). Fig. 5(b) is a side view of the tapered end anti-torsion-cap (50) of Fig. 5(a). In the assembled condition, a receiving area (52) of the cap engages the front tapered end of the stent (54) (shown in phantom.) The anti-torsion cap (50) can be attached to the tapered end (54) by an adhesive or cement such as amyl acrylate which is typically placed in the receiving area (52).

Fig. 5 (c) and 5 (d) depict a further embodiment of the invention in which a torsion resistant arrangement is in the form of an expandable tip member (55) situated at the front end of the leg (54). As illustrated in Figure 5(c), in the initial condition, an outer periphery of the tip member (55) coincides with an outer periphery of the front end of the leg (54). Upon insertion of the stent into the tunnel, the tip member (55) expands further securing proper positioning of the stent. The expandable tip (55) can be made of expandable polymer such as hydrating polymer. In an alternative embodiment, the expandable tip (55) can be made in the form of an inflatable member which is inflated upon insertion of the stent (54) into the tunnel.

Expanding biocompatible polymers are known in the art. Reference is made to Isotalo T, Talja M, Tammela TL, Tormala P, Paasimaa S, Andersson L., "Cytotoxicity testing of a new caprolactone-coated self-expanding bioabsorbable self-reinforced poly-L-lactic acid urethral stent." Urol Res. 1999 Apr;27(2):149-52. This publication discloses a urological stent of bioabsorbable self-expanding self-reinforced (SR) poly-L-lactic acid (PLLA) with a coating of an amorphous copolymer of caprolactone and D,L-lactic acid [P(epsilon-CL/ D,L-LA)]. Also, Sakkers RJ, Dalmeyer RA, de Wijn JR, van Blitterswijk CA, "Use of bone-bonding hydrogel copolymers in bone: An in vitro and in vivo study of expanding PEO-PBT copolymers in goat femora." J Biomed Mater Res 2000 Mar;49(3):312-318. This paper discusses Polyactive(R) [polyethylene oxide-polybutylene terephthalate (PEO-PBT)] which exhibit hydrogel behavior. And also, Steinberg SD, Mayer DA,

Brickman L, Wallack MK, "Regarding: Self-expanding knitted polypropylene mesh facilitates laparoscopic inguinal herniorrhaphy." J Laparoendosc Adv Surg Tech A 1999 Aug;9(4):371-2.

Fig. 6(a) is a semi-perspective view of a stent (62) which is similar in configuration to that of Figs. 1 (a) and 1 (b). The T-shaped scleral-tensioning stent (62) is formed with the leg portion (64) which extends outwardly from the cross-portion or flange (66). As illustrated in Figure 6 (b), in this embodiment the stent in general and the leg portion thereof (64) in particular are formed having arcuate configuration and can be made of an arcuate-biased material. The main portion or a leg (64) of the stent is connected to the flange (66). The stent (62) is formed with at least one longitudinal bore (67) which passes through its entire length. The linear configuration of the stent is maintained by insertion of a counter-arcuate stylet (69) into the bore (67). The counter-arcuate stylet (69) is typically made of a rigid material such as for example, steel or hard plastic. The counter-arcuate characteristics of the stylet shall mean that the stylet has the rigidity sufficient to maintain a straight-lined configuration of the leg portion of the stent despite the arcuate bias. As illustrated in Fig. 6(b), upon removal of the stylet (69), the stent (64) assumes its original arcuate configuration. It is understood that the stylet can have a variety of cross-sectional shapes such as for example, square, round, etc.

Formation of a stent with multiple longitudinal bores adapted for receiving a plurality of counter-arcuate stylets is also contemplated.

Fig 7(a). illustrates another embodiment of a torsion-resistant stent (70) of the invention having a tapered or wedge-shaped insert blade (78) at the front end thereof.

The insert blade (78) can be made of a hard material suitable for surgical use whether natural or synthetic. Such material can be selected from the group including: diamond, zirconium-like gem stones, and hard steels. The insert blade (78) can be removed from the stent after its positioning within the tunnel.

As illustrated in Figure 7 (c) a wedge-shaped insert blade (78) is positioned at the front end of the torsion-resistant stent (70). As illustrated in Fig. 7 (d), the wedge-shaped blade assembly consists of the blade (78) and a guiding stylet (79) extending rearwardly therefrom. Proper orientation of the wedge-shaped blade (78) at the front end of the stent (70) is maintained through the insertion of the guiding stylet (79) in the longitudinal bore (77). Although, various configurations of the guiding stylet (79) and the longitudinal bore (77) are contemplated, in the preferred embodiment of the invention, the stylet and the bore are formed having substantially rectangular cross-section. Close engagement of these elements prevents undesirable rotational motion of the wedge-shaped blade assembly relative to the stent.

Upon proper positioning of the stent within the tunnel, the front end of the assembly including the blade (78) extends outwardly therefrom. Then, the blade- and stylet assembly are pulled outwardly and removed from the stent.

Fig. 8. is a semi- perspective view of another embodiment of the scleral stent (82) of the invention. The leg or main portion (84) extends from the torsion-resistant element or flange (86). The scleral stent (82) is formed with a fixation arrangement facilitating placement of sutures (85) about its outer periphery.

5 Although the stent (82) having the fixation arrangement in the form of a single pair of notches is contemplated, in the preferred embodiment of the invention the fixation arrangement contains multiple pairs of notches situated along the length of the leg (84). As illustrated in Figure 8, one pair of grooves or notches (87) is positioned at a junction between the leg (84) and the flange (86), whereas the
10 other pair of grooves or notches (89) is situated at the front end of the leg portion (84). The sutures (85) are drawn around the stent and run through the underlying sclera and tied or glued in place. Utilization of other types of fixation arrangements such as: clips and staples and the like is also within the scope of the invention.

FIG. 12(a) represents a top plan view of another embodiment of a scleral
15 stent (202) of the present invention. The leg or main portion (204) of the stent is tapered at the front end (201). The flange (206) is designed to provide torsion-resistance. A tapered portion is formed at the front end of the leg or main portion (204). A flange (206) extends transversely to the main portion. In the embodiment of Fig. 12 (a) the thickness of the stent represented by the segment A-B is about
20 600 microns. The total length A-E of the stent is about 5 mm. In some embodiments, the length A-E can be about 4.75mm. The length of each segment A-C and B-K is about 4.5 mm. The length of each segment C-D and K-L is about

250-350 microns, with particular reference to about 300 microns. The length of each segment L- F and D- E is about 500 microns. The length of the segment C-K is between about 600 and 800 microns, with particular reference to about 700 microns. The length of the segment E-F is about 1200 microns. The upper
5 surface of the stent is textured with a groove (222) extending transversely to the direction of the leg or main portion (204). In one embodiment the texture comprises a plurality of grooves about 2/1000 of an inch wide and about 1.5/1000 of an inch deep. Grooves from about 4 /1000 to about 0.7/1000 of an inch are particularly noted as useful texturing elements.

10 Texturing in the form of generally lateral grooving is contemplated using either single or plurality of grooves. Particular note is made to two or more grooves provided at the substantially flat bottom surface of each end of the stent. A stent having grooves formed within side surfaces and/or circumscribing grooves are also contemplated.

15 To facilitate insertion of the scleral stent (202) into the tunnel during the surgery, the front end is formed with a curved and a tapered portion extending from the front end in the direction of flange (206). Total height of the arched stent (202) is 900 microns shown as M-N based on an 8.8 mm base curve. The length of the torsion-resisting substantially flat surface of the tapered end (208) is about
20 500 microns. The torsion-resisting flange element (206) is about 500 microns in width (210). The surface is textured with a grooves (222) traversing the width of the torsion resistance elements (206 and 208).

FIG. 13(a) represents a top view of a scleral stent (242) of another embodiment of the present invention. The leg or main portion (234) of the stent is tapered at the front end thereof (231). The flange (236) provides torsion-resistance. The top and bottom surfaces of the stent are textured with grooves (232) which are traverse to the direction of the longitudinal axis A-A of the main leg or portion (234).

FIG. 13(b) represents a side elevational view of the scleral stent (242) of Fig. 13(a). The front torsion resistant element (236) and the rear torsion resistant element (238) are formed with a plurality of grooves (232) transversing the longitudinal axis of the stent. The interior angle θ of these grooves is about 90° . In one embodiment the grooves are about 1.5/1000 of an inch wide and about 1./1000 of an inch deep.

FIG. 13(c) represents a bottom view of the scleral stent (242) of Fig. 13(a) further illustrating the grooves (232) formed within the torsion resistant elements (236 and 238).

Fig. 14(a) illustrates design of various grooves which can be formed within the stent (400). Groove (402) has generally flat walls positioned to each other at an angle to each other of about 60° . Groove (404) are formed with generally flat walls and two base angles of about 90° each. Groove 406 has a semicircular configuration. Groove (408) forms a part of an ellipse. Groove (410) has interior angles of about 60° and represents a groove opening into a space of greater width.

Groove 412 is formed by the walls having substantially vertical portions interconnected by an arch-shaped member.

Fig. 14(b) represents a textured surface of stent material with the texture elements (414) being exvaginations ("dentals" or "studs") rather than invaginations.

5 Texture elements (415) are trapezoidal in shape.

Fig. 14(c) is a semi-perspective view of a portion of stent material with the texture element (416) in the form of a circumscribing groove.

Fig. 15 is a detailed bottom view of the flange (506) of a stent wherein the texturing is in the form of an arrow shaped groove (532) is provided at the bottom portion thereof. The shape of the groove is directed to permitting inward movement (insertion of a stent) while offering resistance to rearward movement of a stent.

Referring now to figures 16, 16 (a) and 16 (b), wherein a "pull through" device adapted to facilitate a proper positioning of the stent of the invention is within the tunnel is illustrated. A rounded front end (312) of the stent (310) is provided with an attachment opening (314). The attachment opening (314) is designed to receive a pulling arrangement (316), which can be in the form of a cord of a suture material attached to the front end of the stent. In operation, the pulling arrangement (316) can be inserted through the tunnel from either end thereof. The pulling device (316) can be attached to the stent either before or after threading, so as to assist in guiding or pulling the stent into a proper position. In some instances the pulling arrangement is threaded through the sclera in advance of the tunnel

being cut or "formed" (as with a laser or cautery tool). After insertion of the stent, the pulling arrangement (316) is removed. In an alternate embodiment, in order to remove the opening (314), the front end portion (312) can be altered by cutting, melting or abrading. The pulling device or member (316) can be manufactured
5 from a great variety of materials including metallic wire and plastic.

Attachment of the pulling arrangement to the front end of the stent by a variety of connecting arrangements is contemplated by the invention. This includes gluing of the pulling member to the front end of the stent, threaded fittings of the member onto the front end of the stent, or one piece construction of an elongated
10 front end of the stent with a thread-like or needle-like projection of stent material being formed at the front end.

As best illustrated in Fig. 16(a) the rounded front end (312) of the stent (310) is formed with an attachment opening (314). The attachment hole is of 0.34 mm in diameter. Dimensionally, the stent is 600 microns wide at the tip
15 bearing attachment hole (314). The stent is 750 microns wide at A-A as it joins the flange element (306). The total length is 4.75 mm. The top is curved from 200 microns in height at the ends to 900 microns at the center of the long axis (apical height).

Fig. 16(b) illustrates the pulling arrangement (320) in the form of a semi-rigid
20 member having a handle (324) and a stent engagement means (322) adapted for engagement with the opening (314). Upon securing of a connection between these element, an operator can draw the stent into the tunnel.

Although the scleral tensioning stent of the invention having a variety of dimensions is contemplated, in the preferred embodiment of the invention the following dimensions are recommended.

In the present embodiment of the invention, the thickness of the stent represented by the segment A-B is about 600 microns. The total length of the stent represented by the segment A-F is about 5 mm. In some embodiments the length A-F is about 4.75mm. The length of each segment A-K and B-C length is about 4.5 mm. The length of each segment C-D and K-L is about 250-350 microns, with particular reference to about 300 microns. The length of each segment L-F and D-E is about 500 microns. The length of the segment C-K length is about 600 to about 800 microns, with particular reference to about 700 microns. The length of the segment E-F is about 1200 microns.

FIG. 1(b) represents a side elevational view of the scleral stent (2) of Fig. 1(a). The total height M-N of the arched stent (2) is about 900 microns based on an 8.8 mm base curve. To facilitate insertion of the stent into the tunnel during surgery, the front tapered region (12) is provided. Taper is noted as angle θ which is from about 25° to about 45° . The length of the front torsion-resistant element or substantially flat bottom surface (8) is about 500 microns. The length of the substantially flat rear bottom surface (10) performing torsion-resistant function is about 500 microns.

Referring now to FIG. 1(c) which represent a sectional view of the stent according to section line A-A of Fig. 1(b). The height of the segment G-H is about

500 microns, whereas the total height of the segment G-I is from about 700 to about 1000 microns with particular reference to about 900 microns.

As to Fig. 1 (d), the width of the torsion-resistant element or flange (6) is about 1200 microns.

5 Fig. 1(e) is a side view of the stent (2) positioned within a tunnel in the sclera (1). The stent in general and the leg portion (4) in particular are situated within the tunnel in such a manner that the front substantially flat surface (8) and the rear substantially flat surface (10) extend outwardly therefrom.

10 FIG. 1(f) is a side elevation in cutaway showing a stent protruding from a scleral tunnel wherein the stent (2) is positioned within a tunnel in the sclera (1). The stent in general and the leg portion (4) in particular are situated within the tunnel in such a manner that the front substantially flat surface (8) and the rear substantially flat surface (10) extend outwardly therefrom and showing a space (9) between the floor of the scleral tunnel and leg portion (4).

15 Opacification or clouding of the lens of the eye is termed cataract. Cataracts arise from a number of cause, but is particularly noteworthy as a condition associated with advancing age. Without being bound by any particularly theory it is believed that the increasing immobility and lack of flexion associated with aging lenses permits or fosters cataract. The present invention is useful in
20 delaying preventing the occurrence of cataract formation, particularly as related to increased age. In some instances, stent implants will foster the reversal of cataract and the unclouding of a clouded lens.

PRESBYOPIA SURGICAL METHOD

In one embodiment of the surgical procedure such as for presbyopia correction or palliation the first step is to place a drop of 0.5% proparacaine in the eye of a subject being surgically treated. Next, mark the eye at the 12:00 position with the subject seated at a slit lamp, using an 18-gauge sterile needle.

After that, the subject is placed supine upon and the eye is prepped with full strength Povidone-Iodine (Betadine™ Solution). Sterilization preparations which contain soap are not recommended (*e.g.*, Betadine™ Prep). The procedure is performed under monitored local anesthesia. Systemic medications, such as Valium, may be used for relaxation.

A microscope is centered and the eye is draped using a 3M™ 1020 plastic eye drape.

Another drop of 0.5% proparacaine is placed in the eye and a lid speculum is inserted in the conjunctival gutters. The 10:00, 2:00, 4:00 and 8:00 positions are marked, using Gentian Violet or Brilliant Green, using the previously marked 12:00 position as a reference.

Four horizontal incisions of 6mm are made in the conjunctiva tangential to, and approximately 5-7 mm posterior to, the corneal limbus. If required, bi-polar cautery is used for hemostasis. Dissection is performed down through Tenon's Capsule to the sclera and anteriorly over the sclera to the corneal limbus (clearing the area of sclera to be operated).

Marks are made 2 mm to either side of the previously marked 45-degree meridians (10:00, 2:00, 4:00 and 8:00 positions), to map the entrance and exit of each scleral tunnel. Two partial thickness scleral incisions are made with the Diamond Punch Blade™ in the areas of these marks. The incisions should be about 5 250-350 microns deep and parallel to each other at a distance of approximately 4-mm, and 2-3 mm posterior to the corneal limbus.

The Spatula Blade™ is used to tunnel between these two partial thickness incisions. The scleral stents are inserted in the tunnels and positioned, making sure that at least about 350 to 500 microns of the stent protrude out each end of the 10 four tunnels. A tweezers that conforms to the shape of the long axis of the stent just ahead of the flange is useful to hold, manipulate and push the stents into the tunnels, and avoid stent twisting or misplacement. In some surgeries, the tunneling blade will be drawn backwards from the point of entry and reinserted into the tunnel being cut. This permits “pocketing” which leads to difficulty in stent 15 insertion. To avoid pockets, if present, the stent should be inserted into the tunnel from a direction opposite to that from which the tunnel was cut. The tapered first portion of the stent (4) A-B is pushed through the tunnel to protrude beyond the slit. Alternatively, the stent is pulled through by the stent pulling device of Fig. 16(b). In practice, a combination of pulling and pushing is used to insert the 20 stent properly. The flanged rear portion (6) of the stent remains outside the tunnel resting on the sclera.

The conjunctiva is re-approximated with 8-0 Chromic or 8-0 Vicryl running suture. One drop of 1% pilocarpine eye drops, and one drop of Tobradex™ eye drops are administered into the conjunctival gutter. About 500cc of 20% Mannitol are infused intravenously over 30 minutes.

5 In some embodiments this procedure provides expansion of sclera, non-erosion and no ischemia, and about 2-8 diopters increase in amplitude of accommodation and further up to about 10 diopters increase or more.

10 In practice, curing or ameliorating the vision deficit such as presbyopia in a single eye is sufficient to satisfy a subject. In such instances, and give that both eyes are of equal deficit, it is prudent to perform the stent implant in the non-dominant eye. If both eyes are to be treated, operating on one eye and then awaiting recovery before operating on the second eye is useful.

15 Astigmatism is treated by insertion of a stent in the sclera in a "tunnel" in a fashion similar to the presbyopia placement. Except that for astigmatism, placement is, in some embodiments, nearer the lens but not in the visual path than is the case with presbyopia treatment. Also, one to three stents are often sufficient. Placement of the stents is made to raise the outer surface of the lens in from one to three visual quadrants. It is preferred to avoid placing stents at 12, 3, 6 and 9:00 positions to avoid compression of the underlying vasculature. In some
20 embodiments, placement, and then removal and reinsertion of stents after the site of initial insertion has healed is required to reduce astigmatism. The reinsertion is then performed at slightly different positions (advancing clockwise or counter

clockwise) to “tune” the lens perturbation to maximally reduce the underlying lens anomaly that was the cause of the presenting astigmatism.

Claims:

1. A torsion resistant scleral-tensioning stent for positioning in a tunnel formed intrasclerally in a globe of an eye, comprising
- a generally t-shaped body as seen in the intersection arms and having a cross
- 5 portion with a bottom surface and a leg portion extending substantially perpendicularly from a side surface of said cross portion,
- said leg portion having a bottom surface with an arcuate portion and a substantially planar portion at an end of said leg portion distal from said cross portion,
- 10 wherein said arcuate portion has a curvature greater than a radius of curvature of the globe in the area of the tunnel,
- whereby at least a portion of said arcuate bottom surface is adapted to increase the diameter of the scleral size adjacent said tunnel when said stent is positioned in said tunnel; and
- 15 wherein said bottom surface of said cross portion is dimensioned to be disposed external to said tunnel for resisting torsional forces on said leg portion.
2. The stent of Claim 1 wherein said cross portion extends beyond said tunnel.
3. The stent of Claim 2 wherein said arcuate stent has a base curve of from
- 20 about 8 to about 9 mm.
4. The stent of Claim 2 wherein said arcuate stent has a peak of about 7 mm.

5. The stent of Claim 1 wherein is said stent is out-gassing free

6. The stent of Claim 5 comprising thermosetting PMMA.

7. The stent of Claim 1 wherein said stent slopes sharply from a maximum height at the leg-portion to a minimum thickness at the cross portion.

5 8. The stent of Claim 1 wherein said stent is arcuate biased.

9. The stent of Claim 8 further comprising a linear bore hole extending from the flange through the body of the stent.

10. The stent of Claim 8 further comprising a removable stylet positioned within said bore hole.

10 11. The stent of Claim 1 wherein the proximal flanged is flat on the bottom surface.

12. The stent of Claim 1 wherein the distal end of the stent is tapered

13. The stent of Claim 1 further comprising an anti-torsion-cap adapted and configured to conform to the distal end of said stent.

15 14. The stent of Claim 1 wherein the distal end of the stent comprises an insertion blade.

15. The stent of Claim 14 wherein the insertion blade is removable.

16. The stent of Claim 1 further comprising affixation means notches.

17. A torsion resistant scleral-tensioning multi-arcuate-stent comprising at least about four torsion resistant scleral-tensioning stents positioned

(i) about equidistant about the sclera, and

(ii) in non-circulatory-compression arcs.

18. A method of chronically increasing ocular fluid drainage by the steps of placing at least two torsion resistant scleral-tensioning arcuate-stents comprising at least about four torsion resistant scleral-tensioning stents positioned

(i) about equidistant about the sclera, and

(ii) in non-circulatory-compression arcs.

19. A method of chronically reducing ocular fluid out-flow resistance by the steps of placing at least two torsion resistant scleral-tensioning arcuate-stents positioned

(i) about equidistant about the sclera, and

(ii) in non-circulatory-compression arcs.

20. A method of chronic glaucoma palliation by the steps of placing at least two torsion resistant scleral-tensioning arcuate-stents positioned

(i) about equidistant about the sclera, and

(ii) in non-circulatory-compression arcs.

21. A method of presbyopia palliation by the steps of placing at least two torsion resistant scleral-tensioning arcuate-stents comprising at least about four torsion resistant scleral-tensioning stents positioned

(i) about equidistant about the sclera, and

(ii) in non-circulatory-compression arcs.

22. A method of avoiding, delaying, or reversing the lens opacification by the method of placing at least two scleral-tensioning arcuate-stents positioned

(i) about equidistant about the sclera, and

(ii) in non-circulatory-compression arcs.

- ~~23.~~ A method of astigmatism reduction by the steps of placing at least one torsion resistant scleral-tensioning arcuate-stent in an intra-scleral position proximate to the lens and beyond the visual pathway to advance the outward surface of a lens in the quadrant nearest the stent.
- 5

ABSTRACT

A torsion resistant scleral-tensioning stent useful in the correction of presbyopia and further including a method of chronic ocular fluid control utilizing such device.

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"Express Mail" mailing label number EL 571 26 5305 US
Date Of Deposit August 30, 2000
I hereby certify that this paper or fee is being
deposited with the United States Postal Service
"Express Mail Post Office to Addressee" service
under 37 CFR 1.10 on the date indicated above
is addressed to the Assistant Commissioner for Patents,
Box new, Washington, D.C. 20231.
Application Thomas Saunders
(Typed or printed name of person mailing paper or fee)
(Signature of person mailing paper or fee)

FIG. 1(a)

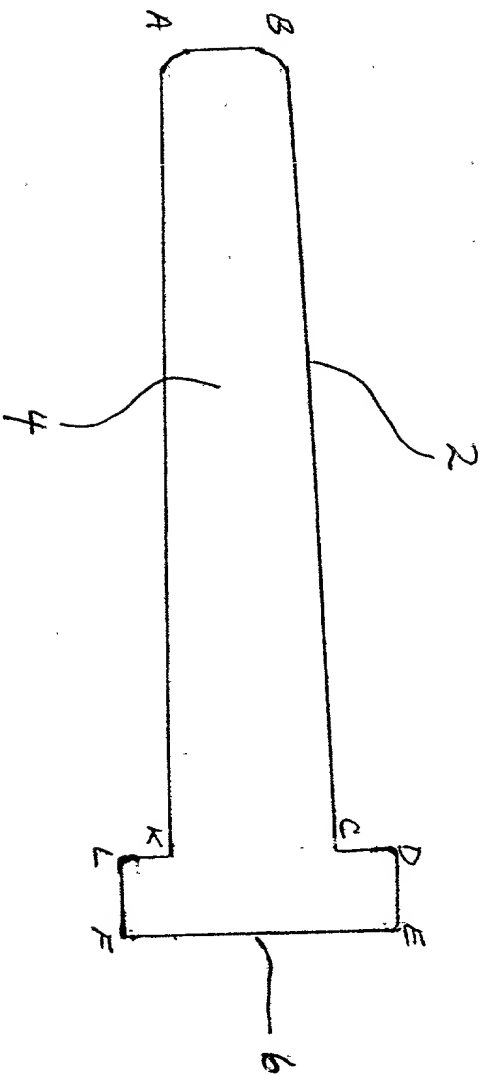


FIG. 1(c)

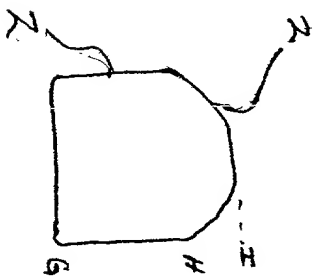


FIG. 1(d)

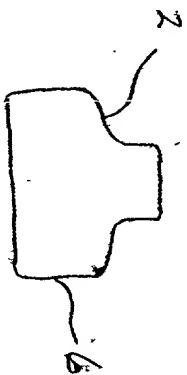


FIG. 1(b)

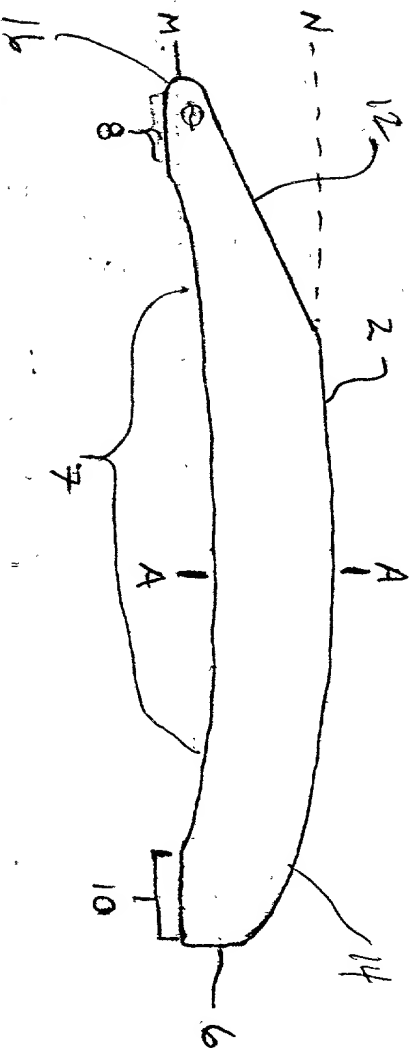


FIG. 1(b) is a side cross-sectional view of the component, showing a long, narrow body 2 with a central horizontal section 4. The body has a vertical section on the right with points A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T, U, V, W, X, Y, Z. A horizontal section 6 is shown at the bottom right. A dashed line 12 is shown on the left side. A point 10 is marked on the bottom surface.

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Fig 1(f)

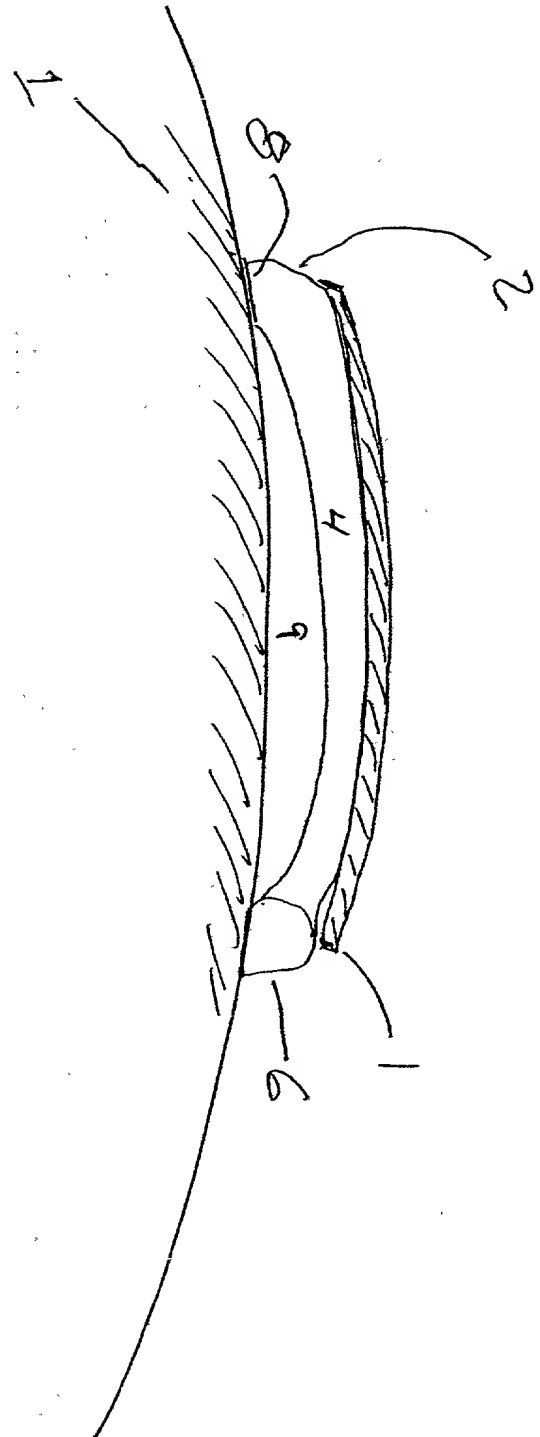


Fig. 2

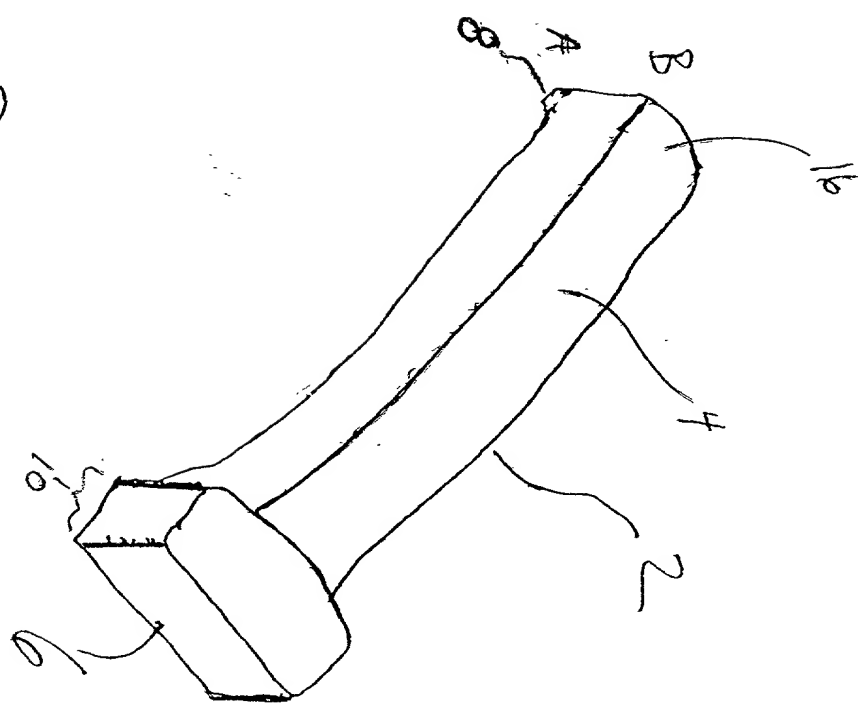


FIG. 2 is a perspective view of the device in accordance with the present invention, showing the main body (2) and the handle (4) in a retracted position. The device is shown in a perspective view, with the main body (2) and the handle (4) being the primary components. The handle (4) is shown in a retracted position, and the main body (2) is shown in a perspective view. The device is shown in a perspective view, with the main body (2) and the handle (4) being the primary components.

FIG. 3(a)

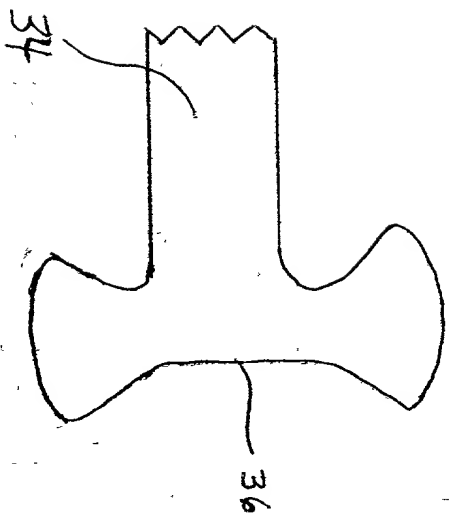


FIG. 3(b)

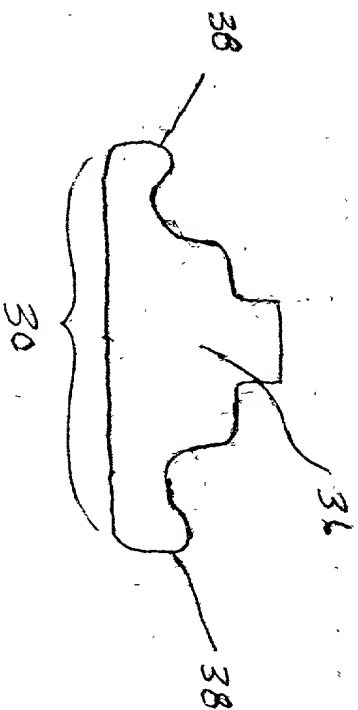


FIG. 4(a)

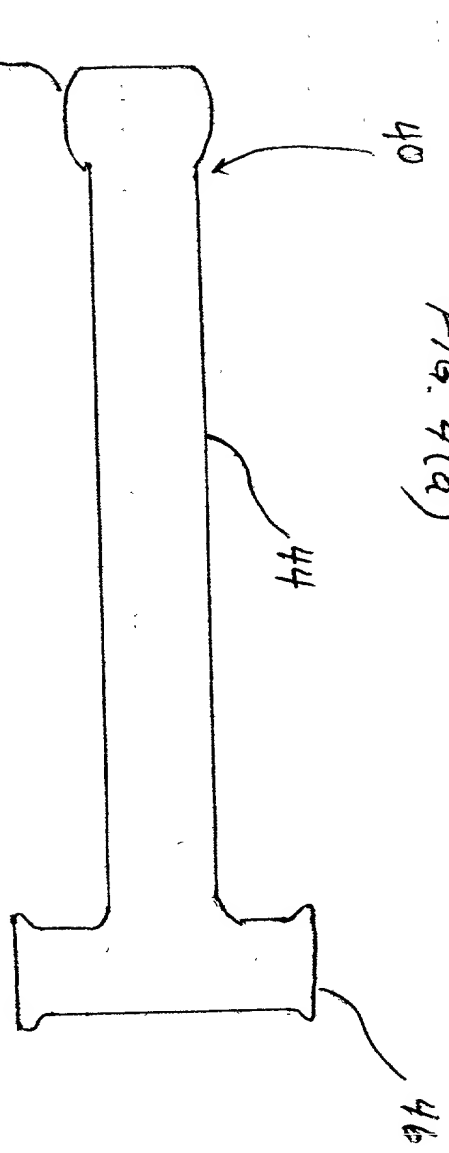


FIG. 4(b)

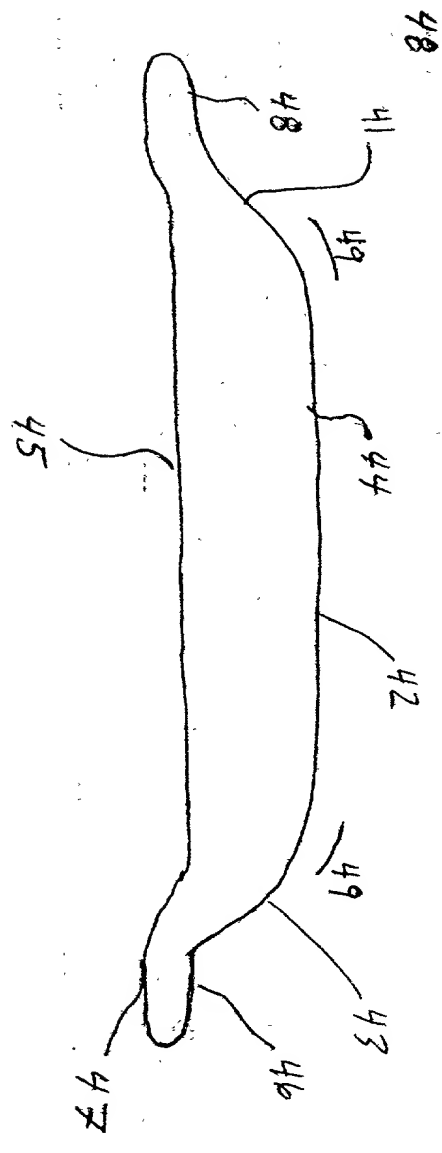


FIG. 5(a)

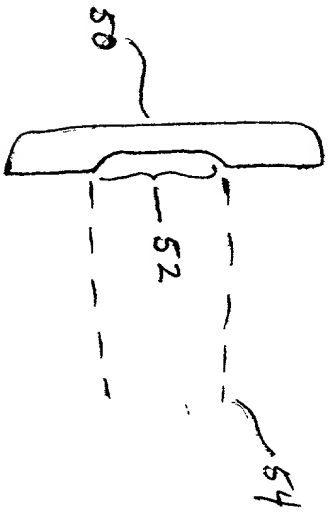


FIG. 5(c)



FIG. 5(b)

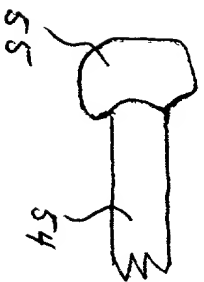
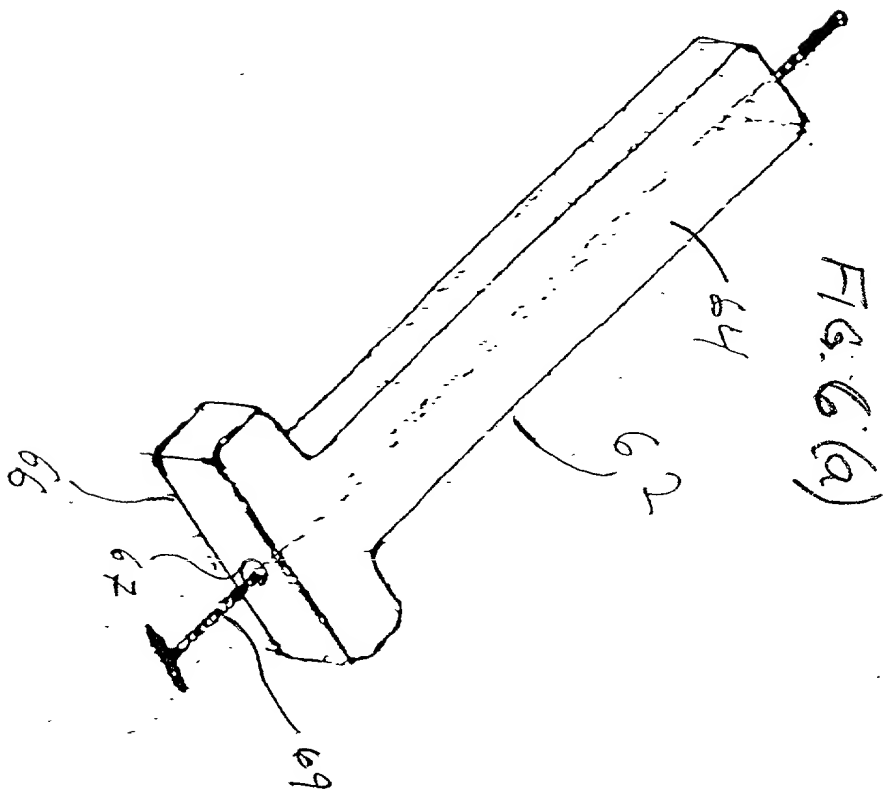
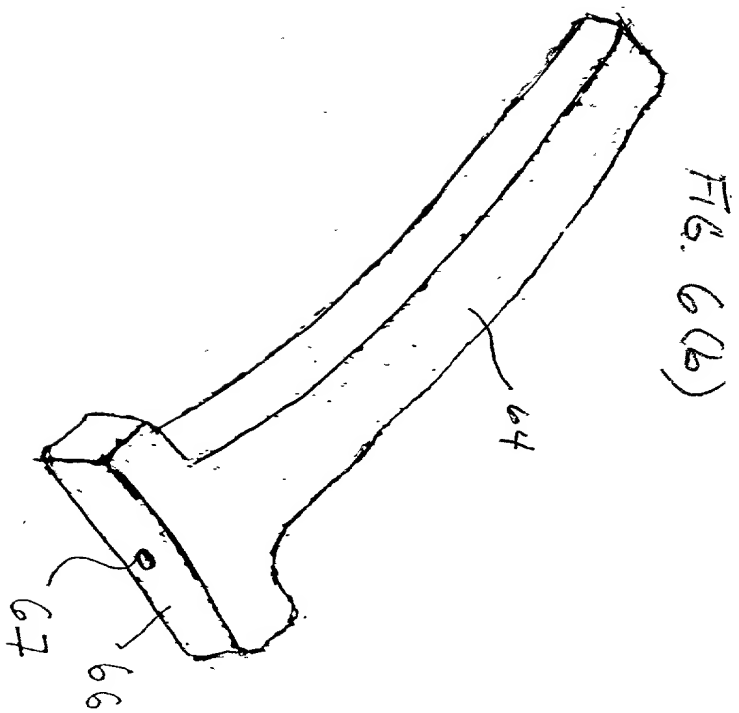


FIG. 5(d)



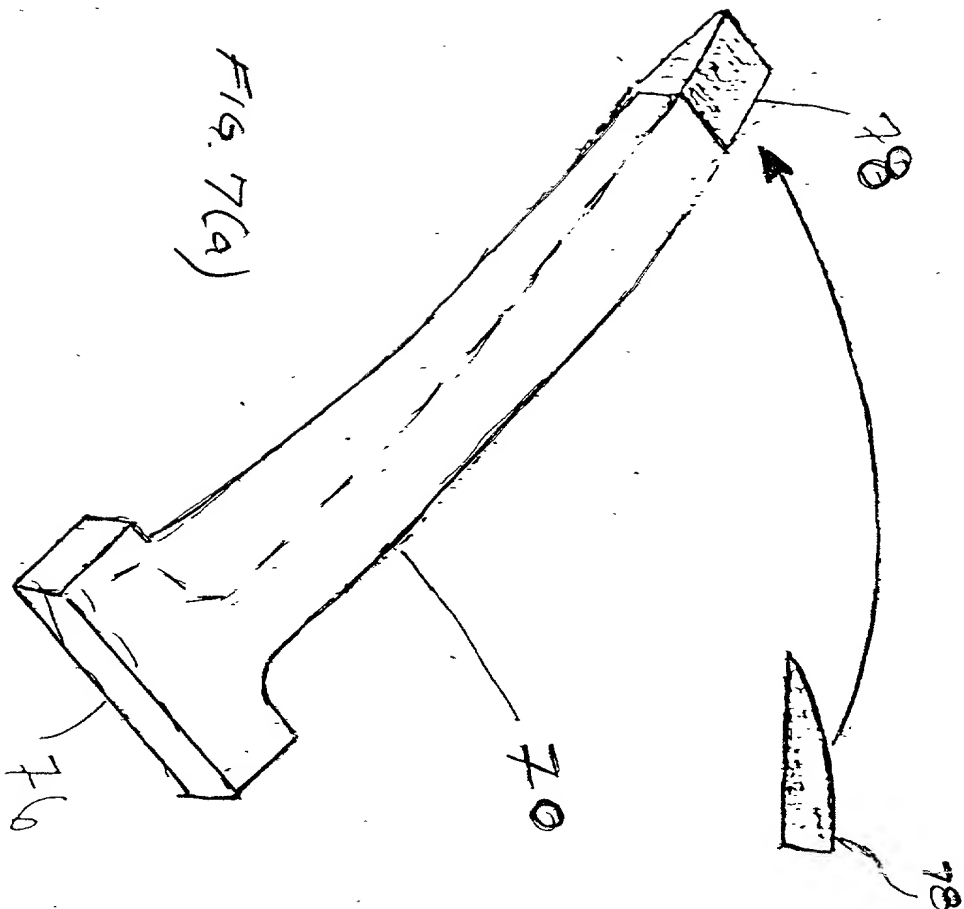
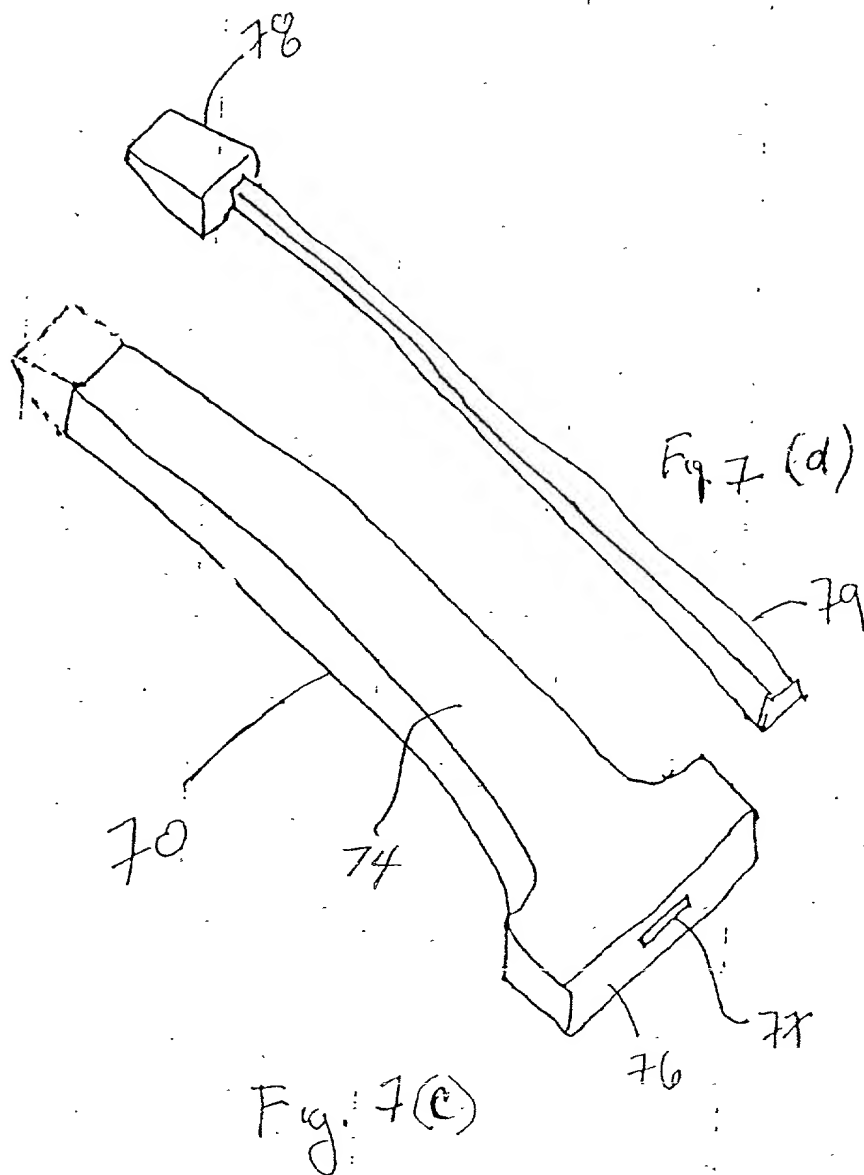


FIG. 7(a)

FIG. 7(b)

FIG. 7(a) is a perspective view of the device of FIG. 1, showing the shaft 70, the block 76, and the block 78. FIG. 7(b) is a perspective view of the device of FIG. 1, showing the shaft 70, the block 76, and the block 78.



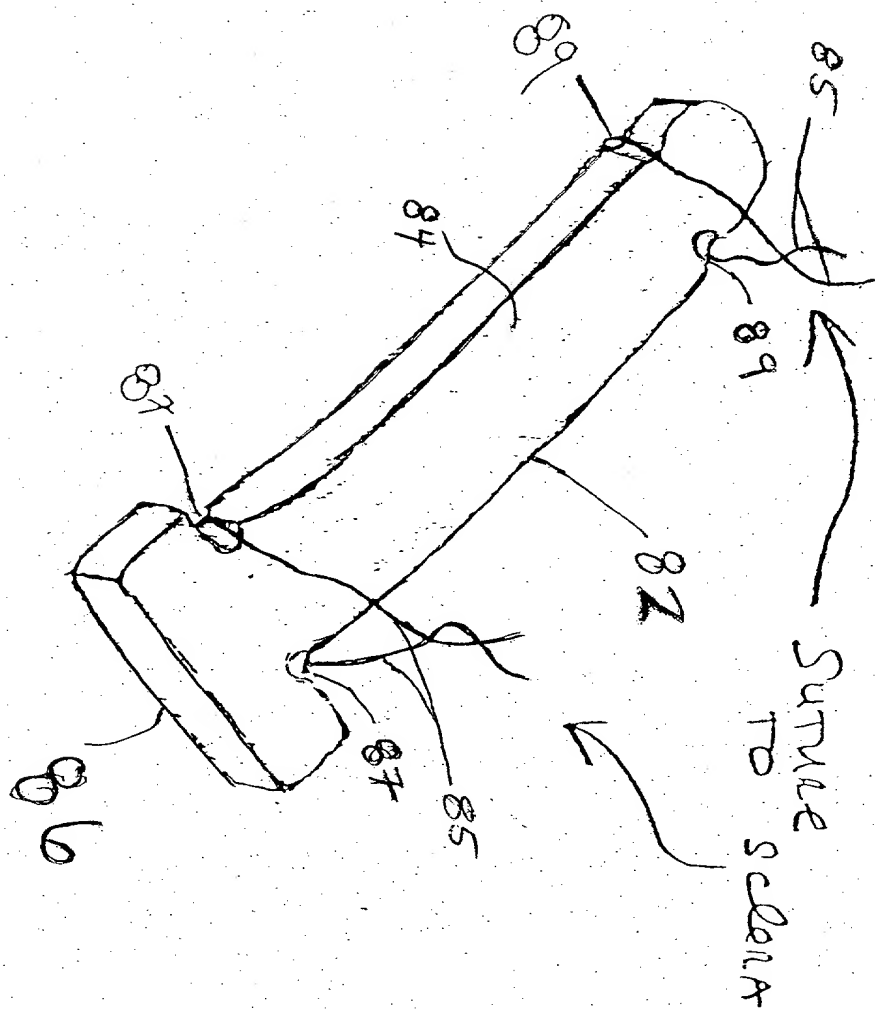
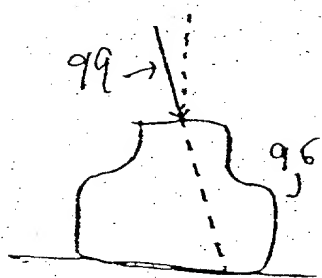


FIG. 8

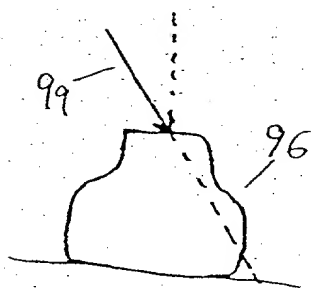
Fig 9(a)



"stable"

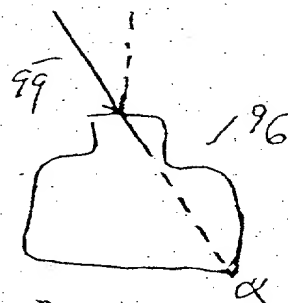
off-axis loading

(b)

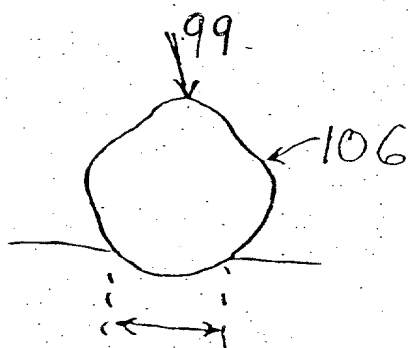


"unstable"

(c)



"critical point"



effective width
of a rounded bottom stent

Fig. 10

FIG. 12 (a)

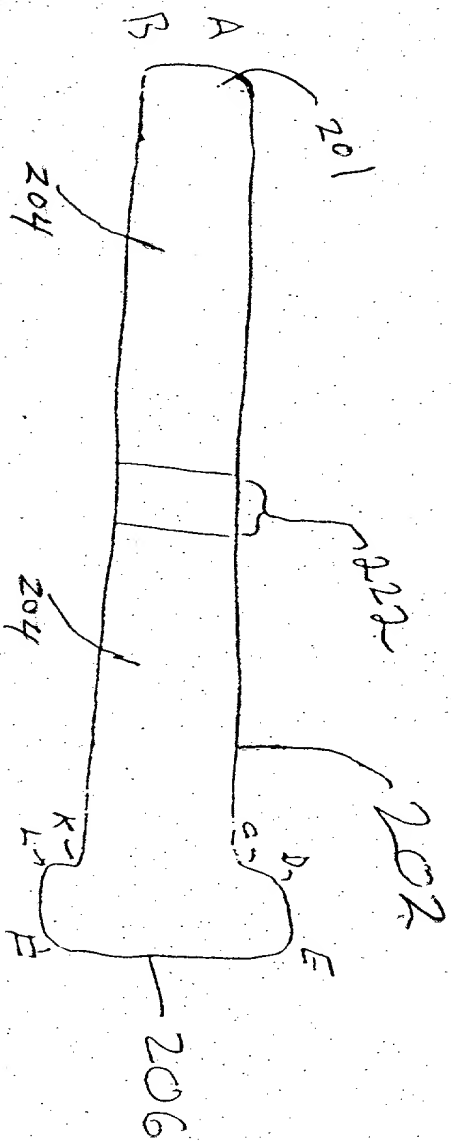


FIG. 12 (b)

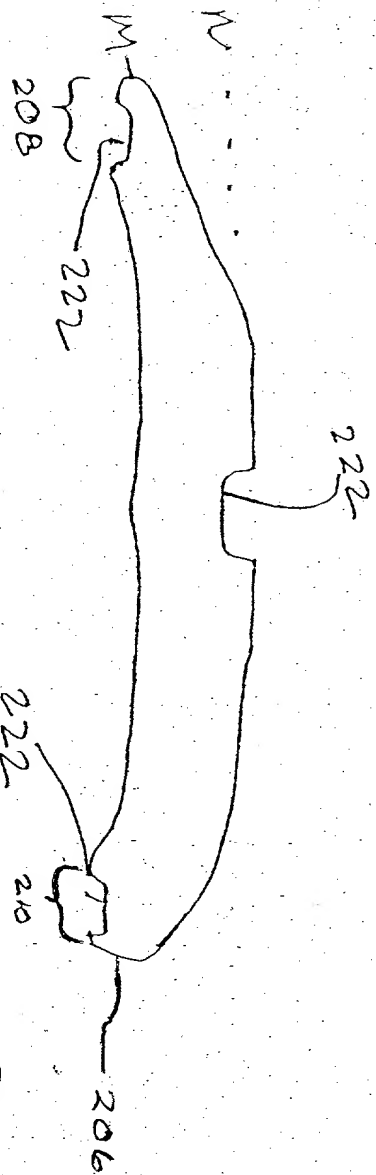


FIG. 12 (c)



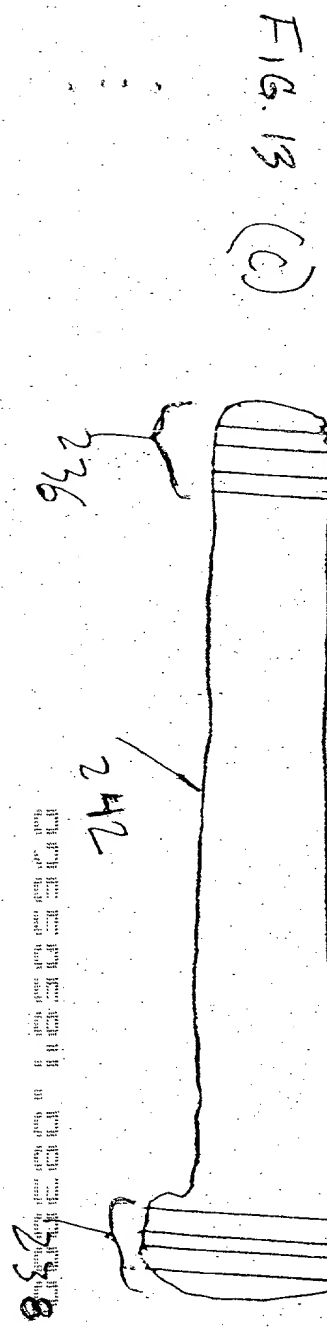
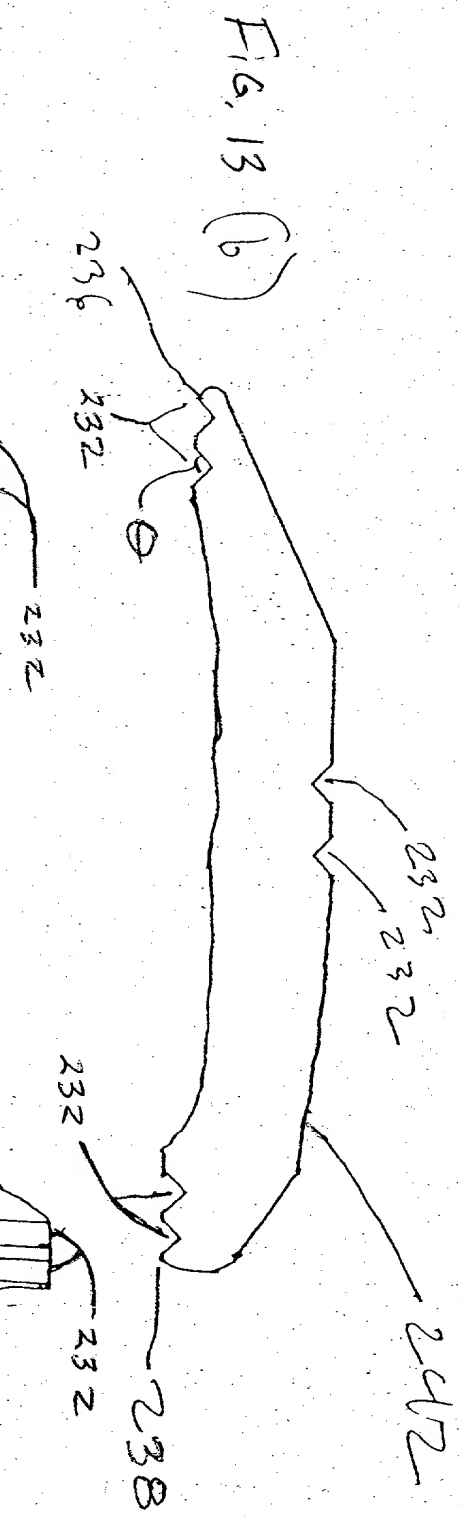
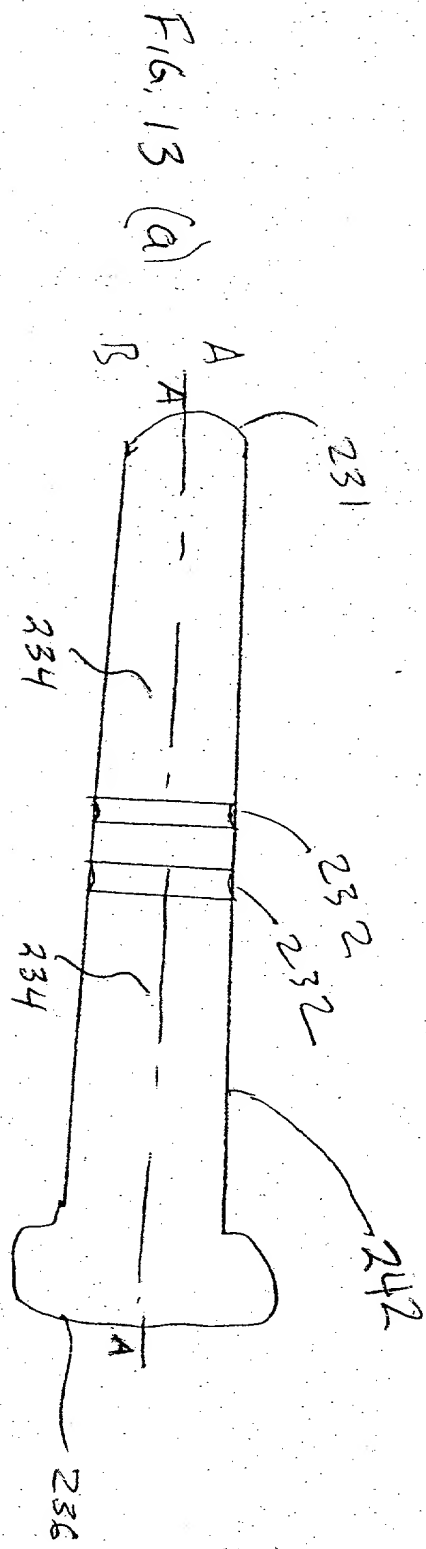


FIG. 14

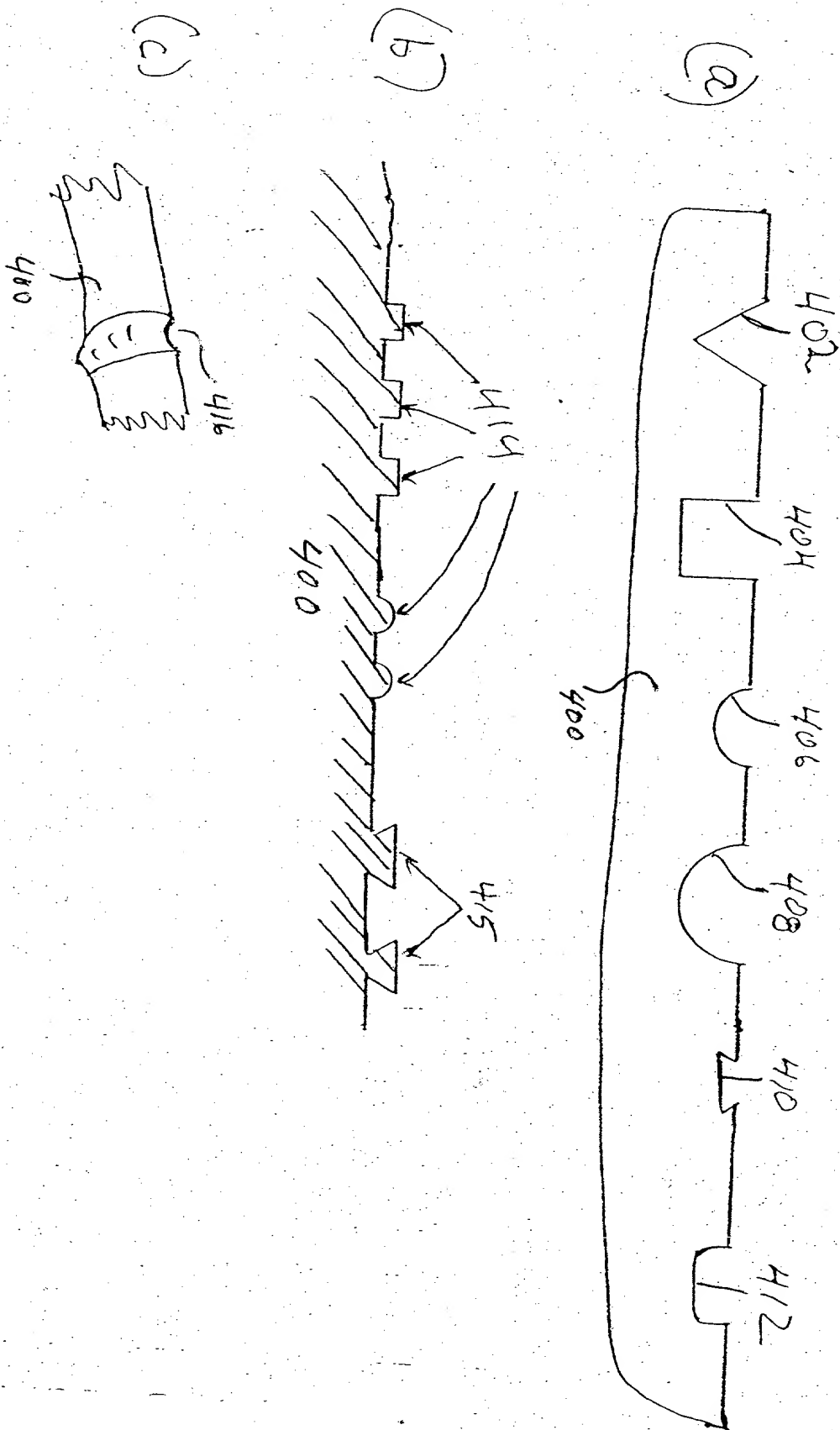


Fig. 15

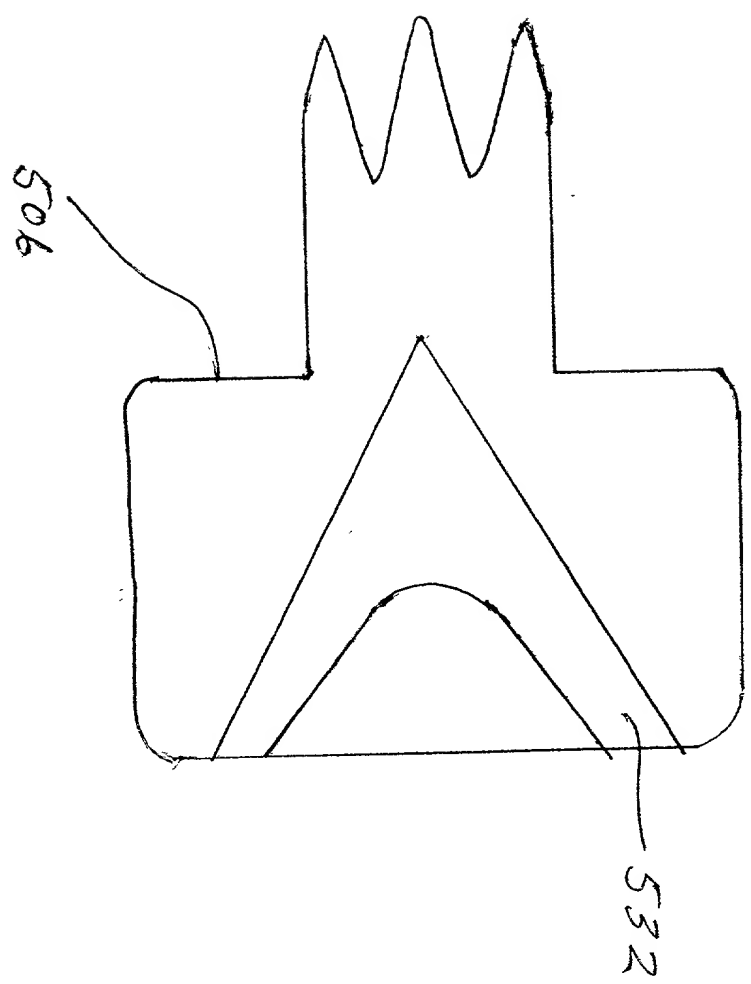


FIG. 15 is a plan view of the device showing the base 506 and the central feature 532.

FIG. 16

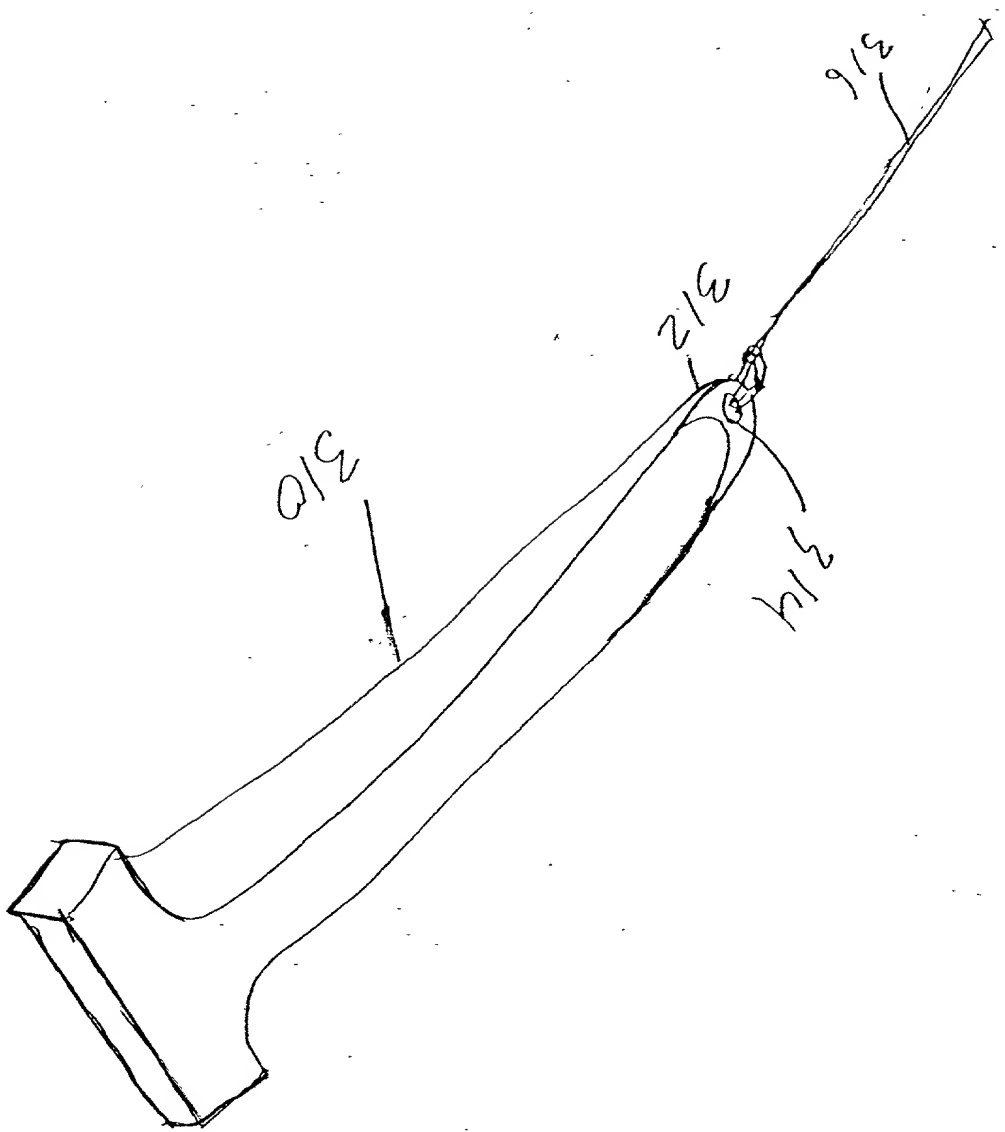


FIG. 16 is a perspective view of the handle assembly of the present invention, showing the handle (3/10) and the handle (3/12) connected by a handle (3/14) and a handle (3/16).

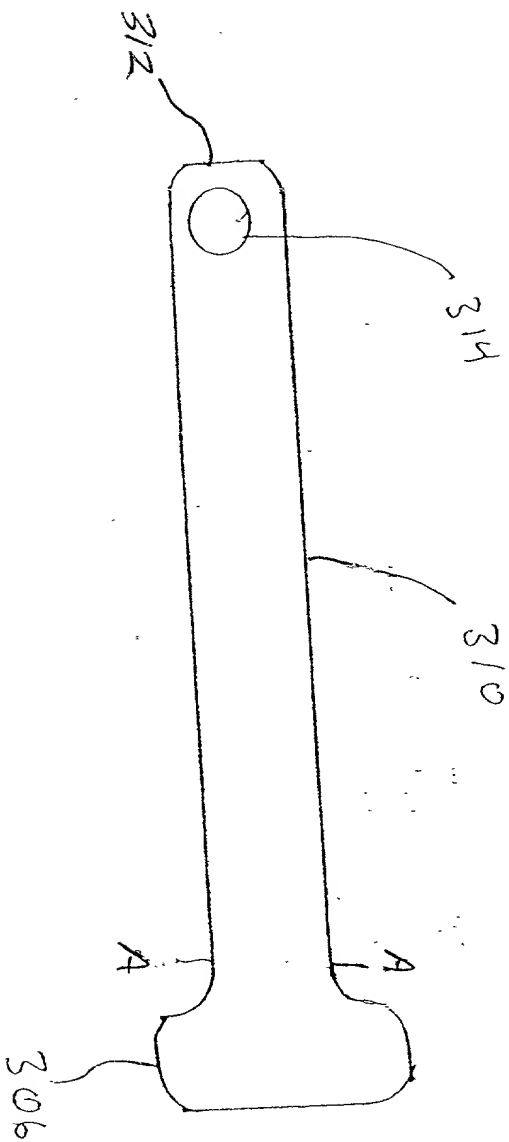
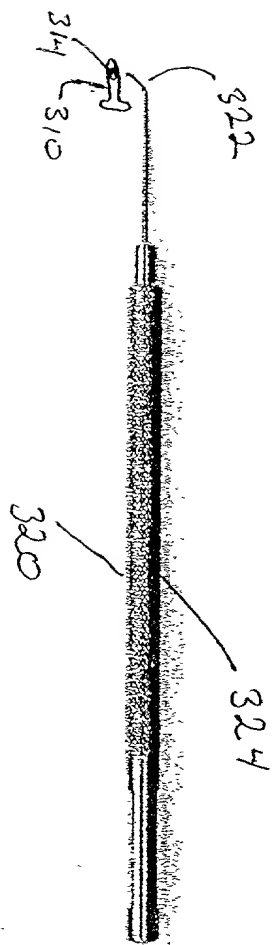


FIG. 16 (a)

Figs. 16 (b)



Docket No.
RES-101A

Declaration For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

OPHTHALMIC DEVICE AND METHOD OF MANUFACTURE AND USE

the specification of which

(check one)

☐ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number _____ and was amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Not Claimed

(Number)

(Country)

(Day/Month/Year Filed)

☐

(Number)

(Country)

(Day/Month/Year Filed)

☐

(Number)

(Country)

(Day/Month/Year Filed)

☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

<u>60/152,455</u>	<u>September 3, 1999</u>
(Application Serial No.)	(Filing Date)
<u>60/178,395</u>	<u>January 27, 2000</u>
(Application Serial No.)	(Filing Date)
<u>60/206,134</u>	<u>May 22, 2000</u>
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, CFR Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

<u>(Application Serial No.)</u>	<u>(Filing Date)</u>	<u>(Status)</u> (patented, pending, abandoned)
<u>(Application Serial No.)</u>	<u>(Filing Date)</u>	<u>(Status)</u> (patented, pending, abandoned)
<u>(Application Serial No.)</u>	<u>(Filing Date)</u>	<u>(Status)</u> (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Howard N. Straub	
Sole or first inventor's signature	Date
Residence 17856 E. Berry Drive, Aurora , Colorado	
Citizenship USA	
Post Office Address Same	

Full name of second inventor, if any	
Second inventor's signature	Date
Residence	
Citizenship	
Post Office Address	

Full name of third inventor, if any	
Third inventor's signature	Date
Residence	
Citizenship	
Post Office Address	

Full name of fourth inventor, if any	
Fourth inventor's signature	Date
Residence	
Citizenship	
Post Office Address	